UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	**MDL No. 2875**
THIS DOCUMENT RELATES TO ALL CASES	**HON. ROBERT B. KUGLER** **CIVIL NO. 19-2875 (RBK)**

PLAINTIFFS' REPLY BRIEF IN SUPPORT OF *DAUBERT* MOTION TO PRECLUDE DEENSE EXPERT JASON O. CLEVENGER FROM OFFERING CLASS CERTIFICATION OPINIONS

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I. INTRODUCTION

Regardless of Dr. Clevenger's qualifications and experience, he does not have a reliable basis for the opinions he offered in this litigation. Dr. Clevenger opines that nitrosamine contaminated valsartan containing drugs (VCDs) are equivalent to the reference-listed drug because the USP monograph for valsartan does not specify a limit for nitrosamines. He says this even though nitrosamines are genotoxic impurities included in the "cohort of concern" per ICH M7, and the USP has publicly stated that nitrosamines are unacceptable impurities in VCDs. Dr. Clevenger also opines that the amount of NDEA in Aurobindo's API is reduced once made into a finished dose. However, Dr. Clevenger only relied on Aurobindo's initial testing data, which was unable to detect NDEA in the same batches that the FDA detected high levels of NDEA. Furthermore, Dr. Clevenger admitted that the FDA found essentially the same amount of NDEA in Aurobindo's finished dose as Aurobindo found in their corresponding API.

II. ARGUMENT

A. The Absence of a Testing Requirement in the USP Monograph Does Not Provide Support for Dr. Clevenger's Opinion that Nitrosamine Contaminated Valsartan is Equivalent to the Reference-Listed Drug

Without providing any support, Defendant claims that it is "demonstrably false" that Dr. Clevenger made "the unsupported and illogical leap that just because the USP monograph doesn't specifically state that valsartan should be tested for nitrosamines (which were not identified as potential impurities due to manufacturers' inadequate risk assessments), that nitrosamine contaminated valsartan is considered pharmaceutically equivalent to the reference-listed drug ('RLD')." (Def. Br. at 3). Dr. Clevenger's expert report clearly states that he based his pharmaceutical equivalency opinion on the lack of a testing requirement in the USP monograph:

> ***As none of the valsartan monographs specifically direct that the material should be tested for nitrosamine impurities***, the valsartan batches at issue met the identical compendial standard, i.e., ***the USP monograph***, of "identify, strength, quality, and purity" to be considered pharmaceutically equivalent to the reference listed drug.

(ECF 2023-8, Clevenger Report at 8 (emphasis added)). Instead of providing support to show that Dr. Clevenger did not make an unsupported and illogical leap based on the absence of a testing requirement in the USP monograph, Defendant merely states that Plaintiffs cannot dispute "that the USP did not specifically require testing for nitrosamines". (Def. Br. at 3).

The lack of a USP testing requirement for nitrosamines does not provide any support to the proposition that the USP considers nitrosamine contaminated valsartan to be equivalent to the RLD. To be sure, for years the USP's website has noted that nitrosamines are "unacceptable impurities" in valsartan containing drugs (VCDs). (ECF 2023-6, USP Nitrosamine Impurities Webpage). Defendant's counter that "even today, the most current monographs for VCDs do not mention nitrosamines" (Def. Br. at 5) only supports Plaintiffs' argument that the absence of nitrosamine testing requirements in the USP monograph is no basis to opine that nitrosamine contaminated VCDs are equivalent to the RLD, as it is absolutely clear that the USP is aware of the potential for nitrosamines in VCDs and considers the presence of nitrosamines in VCDs to be unacceptable across the board. The real question Defendant cannot answer is why NDMA and NDEA were not included in the specifications—again this is because they are not permitted, and Defendant certainly did not identify these impurities in their risk assessments and then test for them, as they were required to do.

Defendant also argues that the amount of nitrosamines present in their VCDs "did not exceed the permitted level of impurities in the monographs." (Def. Br. at 4). This argument is without merit, as already established the USP considers nitrosamines to be "unacceptable impurities" in VCDs. (ECF 2023-6, USP Nitrosamine Impurities Webpage). Defendant's argument that all impurities are equal and allowed to constitute 0.1% of the pill ignores the differing treatment applied to genotoxic impurities in the "cohort of concern" requiring a specific analysis in each case—as occurred here once the FDA was notified of the contaminants. (ICH

M7(R1) 2015, ECF 2090-5 at 9; ICH M7(R1) 2018, ECF 1711-6 at 7). The argument is shown to be even more preposterous when taken to its logical conclusion and applied to an impurity like carfentanil, which is approximately 10,000 times stronger than morphine and fatal at a dose of just 20 micrograms.[1] (Ex. A, Australian Gov't on Fentanyl Availability at 2, citing World Health Organization). Furthermore, Defendant's own internal documents note "as per the latest 'Nitrosamine General Advice letter', USFDA has determined that 'there is no acceptable specification limit for Nitrosamines in drug substances.' In view of USFDA's General Advice, NDMA and NDEA are to be controlled to 'Not Detected' level with the LOD limit equivalent to FDA's published testing methods or lower." (Ex. B, APL-MDL-2875-0023627 at 3744). Ignoring the difference between acceptable and unacceptable impurities is a fatal methodological flaw.

Defendant also notes throughout their brief that the FDA determined that nitrosamines in VCDs were unexpected. (Def. Br. at 5-6). While nitrosamines in VCDs were unexpected to the FDA since the manufacturers of generic valsartan never disclosed the potential of nitrosamine formation in their VCDs to the FDA, the potential for nitrosamines in VCDs was known or knowable to all Defendants.[2] Of import, if nitrosamines in VCDs were unexpected impurities to USP and FDA, then the USP monograph for valsartan wouldn't list nitrosamines. Dr. Clevenger admitted as much himself:

> Q: Are you telling me that you could have .1% fentanyl in these pills and it would be fine?
>
> Mr. Gisleson: Objection to form, that's obnoxious.
>
> Mr. Vaughn: What's your objection?

[1] Nitrosamines are present in many VCDs at levels over 20 micrograms.
[2] A patent submitted in 2013 states "since valsartan impurity K is a nitroso compound that is highly toxic, the control of impurity K in valsartan so that it is not detected is the objective." (Ex. C, ZHP01812101 at 105).

> Mr. Gisleson: Yes, that's obnoxious. It's also a hypothetical that has no foundation whatsoever.
>
> Mr. Vaughn: We're talking about USP. He's saying you can have .1% of any impurity. I want to know if you can have .1% of fentanyl in that pill and be fine.
>
> Mr. Gisleson: Objection.

(ECF 2023-7, Clevenger Depo Tr. 71:12-72:23, 76:14-17 (emphasis added)). Again, Dr. Clevenger mistakenly treats all potential impurities the same, which is methodologically unsound. And if nitrosamines in VCDs were unexpected impurities to USP and USP does not list unexpected impurities in its valsartan monograph as Dr. Clevenger testified, then Dr. Clevenger cannot reliably base his opinion that nitrosamine containing VCDs are equivalent to the RLD on the fact that USP didn't list nitrosamines in its valsartan monograph. Dr. Clevenger should not be permitted to give his unreliable and unsupported opinion that nitrosamine containing VCDs are equivalent to the RLD based on the USP.

B. Dr. Clevenger Has No Basis to Opine that Aurobindo's Risk Assessment met ANDA Requirements

Dr. Clevenger opines that there is a suggestion that Aurobindo met ANDA requirements for conducting a risk assessment because the FDA approved Aurobindo's ANDA. (Clevenger Report at 9-10). However, it is now apparent that Aurobindo did not conduct an adequate risk assessment, and nitrosamine containing VCDs were recalled once the FDA was finally made aware of their presence. Dr. Clevenger opining that the FDA's approval of Aurobindo's ANDA ***suggest*** that Aurobindo's initial risk assessment met ANDA requirements is nothing more than speculation, something an expert opinion should not be based on.

In further "support" of the unreliable opinion that Aurobindo complied with the required ANDA risk assessments, Dr. Clevenger noted that "as part of their root cause investigation, Aurobindo evaluated their key starting materials and manufacturing process for Process II: Toluene route, and they concluded that "there is no possibility for formation of Nitrosamine impurities (NDMA or NDEA) in the process."[3] (Clevenger Report at 10). When asked in deposition if it was his conclusion that there was no possibility for formation of nitrosamine impurities in the process Dr. Clevenger testified "[t]hat was - - that was a quotation from a reference to Aurobindo's final root cause report." (ECF 2023-7, Clevenger Depo Tr. 210:4-14). Dr. Clevenger should not be permitted to parrot a baseless and incorrect conclusion that Aurobindo

[3] Upon seeing Aurobindo's conclusion that there was no possibility for nitrosamine impurities, Aurobindo's non-litigation regulatory consultant unambiguously noted "[redacted]." (ECF 2047-4, APL-MDL-2875-0251669 at 1793 (emphasis added)).

(who hired Dr. Clevenger) came up with during their root cause investigation after getting caught shipping VCDs contaminated with highly potent carcinogens into the United States.

Defendant also argues that because Aurobindo decided to outsource part of their process to a third party that it is untenable to suggest that that Aurobindo could have anticipated their VCDs becoming contaminated. Defendant argues that all the nitrosamines in their VCDs only originated from the API received by a third party and that "Plaintiffs have not presented any evidence" that Aurobindo's synthetic process created nitrosamines.[4] (Def. Br. at 7). This is a liability argument and it is wrong. Aurobindo was required to conduct a risk assessment and to test their API—the fact that the NDEA was introduced through the contaminated recycled solvents they chose to purchase is of no moment. Aurobindo made the decision to utilize recovered solvent instead of spending the money to use fresh solvent to make their VCDs and properly disposing of the solvent afterwards. Aurobindo should have been on heightened alert for the presence of varying impurities in the recovered solvent they were obtaining from a third party. Cutting costs and outsourcing key aspects of the drug development process should have heightened the risk assessments and testing done by Aurobindo, and certainly did not excuse them from conducting a compliant risk assessment.

And most important at this stage, whatever happened was systemic and is appropriate for class wide treatment.

[4] Plaintiffs need not establish that the nitrosamines were solely a result of in-house manufacturing processes at Aurobindo, as opposed to Aurobindo outsourcing and using recycled solvents. This entire argument by Aurobindo is a red herring as they are responsible for the NDEA in their valsartan, however it got there.

C. Dr. Clevenger's Opinion that NDEA Levels Decrease from Aurobindo's API to Finished Dose is Unreliable

1. It's Unclear if Aurobindo Utilized LC-MS or LC-MS/MS Testing Methodology

Defendant claims to have conducted in-house LC-MS/MS, which was "***substantially modelled"*** after an LC-MS/MS approach published by EMEA yet provide absolutely no support for their claims. (Def. Br. at 8 (emphasis added)). It is unclear what Defendant considers "substantially modelled after" to mean as that term is never defined. Defendant also claims that "Aurobindo's testing with LC-MS/MS occurred in December 2018, before the FDA published guidance on testing for nitrosamines that referenced the use of GC-MS." (Def. Br. at 10). Yet, in this litigation Aurobindo produced the FDA document titled "Combined Direct Injection N-Nitrosodimethylamine (NDMA) and N-Nitrosodiethylamine (NDEA) Impurity Assay by **GC/MS**" with metadata indicating that the document is from **October 2018**. (Ex. D, APL-MDL-2875-2803459; Clevenger Depo Tr. 111:23-112:10 (emphasis added)). This discrepancy is unexplained.

Furthermore, it doesn't appear that Aurobindo actually even utilized an LC-MS/MS approach. Aurobindo Pharma Limited, Unit VII did not have the necessary equipment to perform LC-MS/MS, so they sent VCD samples to an external contract laboratory and requested testing. (Ex. E, APL-MDL-2875-0043908 at 909). It appears that in drafting their Aberrant Result Investigation Report that even Aurobindo wasn't sure if LC-MS or LC-MS/MS was utilized, as there is a comment asking, "Is this LC-MS or LC-MS/MS????" (Ex. F, APL-MDL-2875-0102832 at 833). Subsequent drafts of the Aberrant Result Investigation Report note that it was in fact LC-MS testing that was conducted. (Ex. G, APL-MDL-2875-0076155 at 157). Contemporaneous communications further confirm that LC-MS is the testing that was actually conducted: "same has been plan for re analysis along with other batches by LCMS?" (Ex. H, APL-MDL-2875-2721857;

Ex. I, Auro-MDL-2875-0020779). LC-MS is not as sensitive as LC-MS/MS, as Dr. Clevenger explained in his deposition:

[redacted]

> Mr. Gisleson: Look at 26 of 38, look at the last bullet point.
>
> Mr. Vaughn: What was that, John?
>
> Mr. Gisleson: I'm sorry, I was talking to somebody in the room with me. My fault.
>
> Mr. Vaughn: Were you talking to the witness?
>
> Mr. Gisleson: No, I was talking to my – to Steve Hunchuck in the conference room. I didn't realize I wasn't muted.
>
> Mr. Vaughn: Okay.

[redacted]

(ECF 2023-7, Clevenger Depo Tr. 139-18-142:2 (emphasis added) (objections omitted)). When later confronted with Aurobindo's internal documents stating that Aurobindo adopted LC-MS, Dr. Clevenger testified as follows:

[redacted]

(ECF 2023-7, Clevenger Depo Tr. 229:16-230:3 (emphasis added)). At the time of his deposition, Dr. Clevenger wasn't even sure what type of testing Aurobindo performed, which is a problem since he relied on an assumption as to what type of testing was utilized. This pushes his opinions to net opinions.

2. Aurobindo's Spreadsheet Did Not Identify All Test Results

Counter to numerous admissions by Dr. Clevenger, Defendant claims that the spreadsheet Dr. Clevenger relied on[5] contained all of Aurobindo's test results. (Def. Br. at 8). Defendant partially quotes Dr. Clevenger to make it sound as if he testified that he relied on "the most comprehensive dataset that was available and that was the spreadsheet…." (Def. Br. at 9). A review of the transcript reveals that Dr. Clevenger testified that the spreadsheet was the most comprehensive document that the defense attorneys gave to him and even admitted that the spreadsheet did not contain Aurobindo's retesting results or the FDA's non-public results:

[redacted]

[5] This spreadsheet was not even cited in Dr. Clevenger's expert report. (ECF 2023-7, Clevenger Depo Tr. 93:11-94:14, 96:10-22, 180:5-8).

[redacted]

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[redacted]

(ECF 2023-7, Clevenger Depo Tr. 180:5-181:22, 213:11-25 (emphasis added) (objections omitted)). The most comprehensive dataset given to Dr. Clevenger did not contain the most important testing results—Aurobindo's retesting results, which detected high levels of NDEA in the same pills that Aurobindo's original analysis did not detect any NDEA in. This undercuts the basis for his opinions.

Dr. Clevenger repeatedly testified that he never saw Aurobindo's retesting results:

[redacted]

*****

[redacted]

*****

[redacted]

*****

[redacted]

(ECF 2023-7, Clevenger Depo Tr. 139:10-13, 180:23-181:4, 142:21-143:1, 259:13-20 (emphasis added) (objections omitted)). Even if the spreadsheet that Dr. Clevenger relied on included all of the testing results in it (it doesn't), Dr. Clevenger never reviewed Aurobindo's retesting results in forming his opinions, which are more in line with the FDA's results than Aurobindo's initial testing results that Dr. Clevenger relied on. This is a significant problem for his methodology.

3. Dr. Clevenger was Not Provided the Necessary Data to Compare Aurobindo's Internal Testing with the FDA's Testing on the Same Batches

More importantly, Dr. Clevenger was not provided with the necessary information to compare Aurobindo's internal testing and retesting results to the FDA's testing results, which reveals that Aurobindo wasn't initially detecting NDEA in the same VCDs that the FDA was finding above the interim allowable limit. During his deposition, Dr. Clevenger was shown Aurobindo's January 2019 Aberrant Result Investigation Report (ABR/QC/092/18) and testified as follows:

[redacted]

(ECF 2023-7, Clevenger Depo Tr. 129:10-131:9 (emphasis added)). It's not surprising that Aurobindo did not provide Dr. Clevenger with their Aberrant Results Investigation Reports, since Aurobindo incorrectly told the FDA in September of 2019 that there were no aberrant result investigations. The FDA noted the following in the 483 it issued Aurobindo after a surprise inspection:

> Several lists of documents requested were either provided as incomplete, ***inaccurate***, and or explained with ***potentially misleading statements*** throughout the inspection. For example, on 09/24/2019 (day 4 of the inspection), ***two (2) representatives from the Corporate Quality group stated independently that there***

> ***<u>are no Aberrant Results Investigations</u> associated with In-Process testing of product lots*** manufactured at Unit VII. The same quality personnel stated that they are also responsible for review of Aberrant results investigations.
>
> *****
>
> An original Aberrant Investigation Report Form (No. ***ABR/QC/030/19***, date of initiation: 04/08/2019) for Valsartan Tablets, USP 80 batch # VUSB19001, and Amlodipine and Valsartan Tablets USP 10 mg/320 mg batch #s VKSA19001 and VKSA19002, was found in the QA documentation room.[6] ***The 10-page document with attachments*** had the original signatures of the author (signed 04/21/2019) and reviewer (signed 04/22/2019) with no signature of the final QA approver. **Your DGM-QA stated that the document was intended for <u>destruction</u>**. However, no explanation was provided when the index list of 2019 Aberrant Investigation Reports had ABR/QC/030/19 listed as "closed" investigation. This aberrant investigation report was initiated to investigate the below LOQ results obtained and reported for the NDEA content in the batches listed above.

(Ex. K, APL-MDL-2875-0024066 at 76-77 (emphasis added)). It appears that the FDA was unaware of Aberrant Result Investigation Report (ABR/QC/092/18) from eight months earlier that shows Aurobindo unable to detect NDEA in the same pills the FDA was finding high levels of NDEA in. Furthermore, after thorough review, it does not appear that Aurobindo has produced to Plaintiffs in this litigation the 10-page version of ABR/QC/030/19 with attachments and signatures that they told the FDA they were going to destroy. Plaintiffs have only been produced an 8-page version of ABR/QC/030/19 without any attachments or signatures. (Ex. L, APL-MDL-2875-1515785). It does not appear that the FDA or the Plaintiffs in this litigation have been given all of Aurobindo's testing results and documents, much less Dr. Clevenger. Regardless, Dr. Clevenger is relying on Aurobindo's original testing data, which is unreliable and incomplete because Aurobindo was unable to detect NDEA in the same pills that the FDA detected high levels of NDEA in. This is yet another methodological shortcoming.

[6] The "comprehensive" spreadsheet that Dr. Clevenger allegedly relied on (Ex. J, Auro-MDL-2875-0104586) does not contain any testing results for these three batches.

4. Information Regarding the FDA's Testing Methods was Available, but Not Given to Dr. Clevenger

Defendant appears to then question the accuracy of the FDA's testing results, incorrectly claiming that the "FDA did not provide any details of how it conducted GC-MS on the samples." (Def. Br. at 9). The FDA notified Aurobindo that it tested their VCDs with Headspace GC/MS and then confirmed those results with Direct Injection GC/MS. (Ex. M, Auro-MDL-2875-0105928 at 29). Defendant's argument that "Dr. Clevenger had 'no basis to criticize the FDA's testing method' because the FDA did not provide any information is not consistent with reality or Dr. Clevenger's testimony:

[redacted]

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[redacted]

[redacted]

(ECF 2023-7, Clevenger Depo Tr. 123:4-15, 138:5-139:8 (emphasis added)). Information regarding the FDA's testing methods were available, they just weren't given to Dr. Clevenger. Yet another problem and red flag for a net opinion.

5. None of Aurobindo's Initial Testing Results are Consistent with the FDA's Testing Results on the Same Batches

Defendant attempts to minimize the FDA's testing results because the FDA only tested 1.4% of the batches that Aurobindo tested. (Def. Br. at 11). The more relevant metric is that 0% of Aurobindo's initial testing results, which are what Dr. Clevenger solely relied on, correspond with the results for the batches that the FDA tested via two different methods. (ECF: 2047-7, APL-MDL-2875-0102832 at 835). Upon being shown Aurobindo's initial testing results compared to the FDA's results for the first time, Dr. Clevenger agreed that Aurobindo's initial testing results were significantly different from the FDA's confirmed testing results:

[redacted]

[7] Dr. Clevenger conceded in deposition that these Aurobindo testing results were obtained via LC-MS. These exact same results later appear in the spreadsheet that Dr. Clevenger relied on, but are instead noted to be from LC-MS/MS.

[redacted]

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[redacted]

(ECF 2023-7, Clevenger Depo Tr. 132:11-134:2, 134:20-135:20 (emphasis added) (objections omitted)). The significant difference between Aurobindo's initial testing results compared to the verified testing results from the FDA undermines the reliability of all of Aurobindo's initial testing results. Aurobindo's non-litigation regulatory consultant told Aurobindo as much, "[redacted]" (Ex. N, APL-MDL-

2875-0135474 at 77-78). An expert opinion cannot be based on a biased, inaccurate, unreliable methodology with poor reproducibility.

6. Aurobindo's Retesting Results are More Consistent with the FDA's Results Than Aurobindo's Initial Results, Which Dr. Clevenger Relied On

Equally important, upon reviewing Aurobindo's retesting results compared to the FDA's results for the first time, Dr. Clevenger agreed that Aurobindo's retesting results were more consistent with the FDA's results than Aurobindo's original results were—yet Dr. Clevenger relied on Aurobindo's original testing results:

[redacted]

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[redacted]

(ECF 2023-7, Clevenger Depo Tr. 143:15-22, 144:12-16 (emphasis added)). Aurobindo's own retesting results, which Dr. Clevenger did not review in forming his opinion, provide further support to the accuracy of the FDA's testing results and the inaccuracy of Aurobindo's initial testing results, which Dr. Clevenger relied on. Dr. Clevenger's methodology cannot be deemed reliable under these circumstances.

7. Aurobindo's API Testing via GC-MS is Consistent with the FDA's Finished Dose Testing Results on Corresponding Batches via GC-MS

While the LC-MS testing Aurobindo performed on their VCDs did not follow the FDA's testing guidance, Aurobindo did follow the FDA's guidance and actually utilized GC-MS to test their API. In response to the FDA finding discrepancies with Aurobindo's nitrosamine testing, Aurobindo told the FDA that Aurobindo's "***results of corresponding API are in trend with Finished product testing results at FDA***." (Ex. O, Auro-MDL-2875-0020671 at 72 (emphasis added)). Aurobindo now offers Exponent/Dr. Clevenger in this litigation to give an opinion

counter to what Aurobindo told the FDA—that API results are higher than finished product results. "A plaintiff must set forth two elements to prove regulatory estoppel: (1) a party made a statement to a regulatory agency; and (2) afterward, the party took a position opposite to the one presented to the regulatory agency." *Kessler Dental Associates, P.C. v. Dentists Insurance Company*, 505 F. Supp. 3d 474, 479 (E.D. PA 2022). New Jersey first applied the estoppel doctrine in a regulatory context nearly 30 years ago. *Morton Intern., Inc. v. General Acc. Ins. Co. of America*, 134 N.J 629 A.2d 831, 874 (1993). Defendant should be estopped from offering an expert to take a position opposite to the one Defendant presented to the FDA.

After seeing Aurobindo's API results compared to the FDA's finished dose results for the first time, Dr. Clevenger agreed with what Aurobindo previously admitted to the FDA—that Aurobindo's API results via GC-MS are essentially the same as the FDA's finished dose results via headspace GC-MS and direct injection GC-MS:

[redacted]

[8] [redacted] (Ex. O, Auro-MDL-2875-0020671 at 72 (emphasis added)).

(ECF 2023-7, Clevenger Depo Tr. 171:9-173:2 (emphasis added) (objections omitted)). The FDA's testing results are further corroborated by Aurobindo finding essentially the same amount of NDEA in their API as the FDA found in the corresponding finished doses. Furthermore, Dr. Clevenger admitting that Aurobindo detected essentially the same amount of NDEA in their API as the FDA detected in corresponding finished doses undermines Dr. Clevenger's core opinion—that the amount of NDEA is lower in Aurobindo's "finished drug products than the corresponding API batches used to manufacture the drug product." (Def. Br. at 10). Dr. Clevenger cannot reliably opine that the amount of NDEA in Aurobindo's API decreases when it is made into pill form, as this is contradicted by the reliable data and he provides no scientific explanation based on the reliable data.

8. Aurobindo's NDMA Results Comport with the FDA's NDMA Results; Aurobindo's NDEA Results do Not Comport with the FDA's NDEA Results

Defendant ended their brief by claiming that Plaintiffs took a contrary position on the reliability of Aurobindo's testing methodology in responding to a Motion to Compel Dr. Najafi discovery by relying "on the accuracy of Aurobindo's test results to claim that Valisure's test results were inaccurate." (Def. Br. at 12). Plaintiffs' Response to Defendants' Motion to Compel Dr. Najafi discovery discussed NDMA testing results, while Plaintiffs' present Motion to Preclude Dr. Clevenger is focused on NDEA testing. Aurobindo's new counsel argues that Plaintiffs

"cannot have it both ways", but neglects to acknowledge that Aurobindo's NDMA testing results indicating an absence of NDMA were confirmed by results obtained by the FDA on the same batches,[9] while Aurobindo's NDEA test results are significantly different from the FDA's results. The FDA tested Aurobindo's VCDs with headspace GC-MS and direct injection GC-MS and were unable to detect any NDMA. Aurobindo also did not detect NDMA in their VCDs via LC-MS. Aurobindo not being able to detect NDMA in their VCDs comports with multiple FDA testing results on the same batches. Aurobindo's NDMA testing results that showed no NDMA in the pills the FDA tested were likely accurate, because a regulatory body came to the same result on the same batch of pills with multiple testing methods. However, as discussed above, Aurobindo was unable to detect NDEA in the same batch that the FDA found NDEA in with both of its testing methods. Therefore, Aurobindo's NDEA testing results that showed no NDEA in the pills the FDA tested were inaccurate, because a regulatory body came to a different result on the same batch of pills with multiple testing methods. Defendant's argument that Plaintiffs have taken a contrary position is misleading and without merit.

Dr. Clevenger relied on Aurobindo's initial testing results, which are unreliable, in part because Aurobindo was unable to detect NDEA in the same batches of VCDs that the FDA detected high levels of NDEA in via multiple methodologies. The only other thing Dr. Clevenger relied on was a pilot study conducted by Aurobindo, which was also based on Aurobindo's unreliable initial testing results. The very foundation of Dr. Clevenger's opinion that the amount of NDEA in Aurobindo's API decreases when made into a pill is based on inaccurate and unreliable testing results, which is fatal to his opinion.

[9] The FDA also found below the level of detection (LOD) of NDMA in all lots of Aurobindo VCDs tested. (Ex. P, PRINSTON00144343 at 44; Compare to Ex. J).

III. CONCLUSION

For the foregoing reasons, Dr. Clevenger should be precluded from offering his opinion that nitrosamine contaminated VCDs are equivalent to the RLD, and that the amount of NDEA in Aurobindo's API is reduced when made into a finished dose pill.

Dated: June 16, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 16th day of June 2022, I caused a true and correct copy of the foregoing to be filed and served upon all counsel of record by operation of the Court's CM/ECF system. In addition, I certify that unredacted copies of foregoing document will be served contemporaneous to filing via email on the Court, Special Master, and the Defense Executive Committee at DECValsartan@btlaw.com.

/s/ C. Brett Vaughn
C. Brett Vaughn